Complete Summary

GUIDELINE TITLE

American Association of Clinical Endocrinologists, The Obesity Society, and American Society for Metabolic & Bariatric Surgery medical guidelines for clinical practice for the perioperative nutritional, metabolic, and nonsurgical support of the bariatric surgery patient.

BIBLIOGRAPHIC SOURCE(S)

Mechanick JI, Kushner RF, Sugerman HJ, Gonzalez-Campoy JM, Collazo-Clavell ML, Guven S, Spitz AF, Apovian CM, Livingston EH, Brolin R, Sarwer DB, Anderson WA, Dixon J. American Association of Clinical Endocrinologists, The Obesity Society, and American Society for Metabolic & Bariatric Surgery Medical guidelines for clinical practice for the perioperative nutritional, metabolic, and nonsurgical support [trunc]. Endocr Pract 2008 Jul-Aug;14 Suppl 1:1-83. [777 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

These clinical practice guidelines (CPG) will expire in 2011 and will be updated by American Association of Clinical Endocrinologists (AACE), the Obesity Society (TOS), and American Society for Metabolic and Bariatric Surgery (ASMBS) at a time determined by the societies.

**** REGULATORY ALERT ****

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- December 3, 2008, Innohep (tinzaparin): The U.S. Food and Drug Administration (FDA) has requested that the labeling for Innohep be revised to better describe overall study results which suggest that, when compared to unfractionated heparin, Innohep increases the risk of death for elderly patients (i.e., 70 years of age and older) with renal insufficiency. Healthcare professionals should consider the use of alternative treatments to Innohep when treating elderly patients over 70 years of age with renal insufficiency and deep vein thrombosis (DVT), pulmonary embolism (PE), or both.
- February 28, 2008, Heparin Sodium Injection: The U.S. Food and Drug Administration (FDA) informed the public that Baxter Healthcare Corporation has voluntarily recalled all of their multi-dose and single-use vials of heparin

sodium for injection and their heparin lock flush solutions. Alternate heparin manufacturers are expected to be able to increase heparin production sufficiently to supply the U.S. market. There have been reports of serious adverse events including allergic or hypersensitivity-type reactions, with symptoms of oral swelling, nausea, vomiting, sweating, shortness of breath, and cases of severe hypotension.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Overweight and obesity (class 3 obesity, extreme obesity, clinically severe obesity, and morbid obesity)
- Obesity comorbidities
- Complications of bariatric surgery

GUIDELINE CATEGORY

Counseling
Evaluation
Management
Risk Assessment
Treatment

CLINICAL SPECIALTY

Cardiology
Colon and Rectal Surgery
Endocrinology
Family Practice
Gastroenterology
Internal Medicine
Nutrition
Psychology
Pulmonary Medicine

Rheumatology
Surgery

INTENDED USERS

Advanced Practice Nurses
Dietitians
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide the following:

- An overview of the important principles of bariatric surgery as context for interpretation of subsequent evidence-based recommendations
- An evidence-based resource for the perioperative nonsurgical management, especially nutritional and metabolic support, of the bariatric surgery patient
- Specific recommendations regarding the selection of appropriate patients for bariatric surgery
- Specific recommendations regarding the preoperative evaluation for the bariatric surgical patient
- Specific recommendations regarding postoperative nonsurgical management of the bariatric surgery patient
- Specific recommendations regarding the recognition and management of postoperative complications
- Specific recommendations regarding selection of patients for a second (staged) bariatric surgical procedure or a revision or reversal of a previous bariatric surgical procedure

TARGET POPULATION

- All patients with a body mass index (BMI) of ≥40 kg/m^2, regardless of the presence of comorbidities, are potential candidates for bariatric surgery.
- Patients with less severe obesity (BMI ≥35 kg/m^2) could be considered if they had high-risk comorbid conditions such as life-threatening cardiopulmonary problems (for example, severe sleep apnea, Pickwickian syndrome, or obesity-related cardiomyopathy) or uncontrolled type 2 diabetes mellitus (T2DM).
- Patients with BMIs between 35 and 40 kg/m^2 that have obesity-induced *physical* problems interfering with lifestyle (for example, joint disease treatable but for the obesity, or body size problems precluding or severely interfering with employment, family function, and ambulation)

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation/Management

1. Preoperative evaluation and management including
    - Medical history, physical examination, and appropriate laboratory tests

- Education regarding risks and benefits of bariatric surgery, procedural options, and financial counseling
- Optimizing glycemic control
- Treatment of dyslipidemia
- Discontinuing estrogen therapy if applicable
- Cardiology consultation and beta-adrenergic blockade if indicated
- Chest radiograph
- Pulmonary evaluation, including arterial blood gas measurement and polysomnography if indicated
- Smoking cessation
- Diagnostic evaluation for deep venous thrombosis (DVT) and vena cava filter if indicated
- Abdominal ultrasonography and viral hepatitis screen
- Psychosocial-behavioral evaluation
- Nutritional evaluation

2. Early postoperative care including
    - Consultation with a dietitian and staged meal progression; multiple small meals, balanced meal plan; considering parenteral nutrition (PN) in high-risk patients
    - Maintaining appropriate blood glucose level; use of insulin analogue if indicated
    - Beta-adrenergic blockers if necessary
    - Pulmonary management
    - Prophylaxis against DVT
    - Monitoring for surgical complications, including anastomotic leaks and rhabdomyolysis
    - Fluid management
    - Blood transfusion if indicated

3. Late postoperative management
    - Assessment of weight loss
    - Patients should be advised to increase their physical activity
    - Management of nutritional deficiencies (vitamin and mineral supplementation; oral ferrous sulfate, fumarate, or gluconate; intravenous iron infusions)
    - Bone density measurement and treatment with bisphosphonates if indicated
    - Assessment of lipid level and therapy with lipid-lowering medication
    - Management of gastrointestinal complications
    - Body-contouring surgery
    - Patients should be encouraged to participate in ongoing support groups

4. Hospital admission if indicated

MAJOR OUTCOMES CONSIDERED

- Effectiveness of bariatric surgery for obesity comorbidities
- Weight loss
- Morbidity and mortality related to bariatric surgery
- Benefits and risks of bariatric surgery

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Scientific Substantiation in Evidence-Based Medicine*

Level	Description	Comments
1	Prospective, randomized, controlled trials—large	Data are derived from a substantial number of trials, with adequate statistical power involving a substantial number of outcome data subjects Large meta-analyses using raw or pooled data or incorporating quality ratings Well-controlled trial at one or more centers Consistent pattern of findings in the population for which the recommendation is made (generalizable data) Compelling nonexperimental, clinically obvious, evidence (for example, use of insulin in diabetic ketoacidosis); "all-or-none" indication
2	Prospective controlled trials with or without randomization—limited body of outcome data	Limited number of trials, small population sites in trials Well-conducted single-arm prospective cohort study Limited but well-conducted meta-analyses

Level	Description	Comments
		Inconsistent findings or results not representative for the target population Well-conducted case-controlled study
3	Other experimental outcome data and nonexperimental data	Nonrandomized, controlled trials Uncontrolled or poorly controlled trials Any randomized clinical trial with 1 or more major or 3 or more minor methodologic flaws Retrospective or observational data Case reports or case series Conflicting data with weight of evidence unable to support a final recommendation
4	Expert opinion	Inadequate data for inclusion in level 1, 2, or 3; necessitates an expert panel's synthesis of the literature and a consensus Experience-based Theory-driven

* Levels 1, 2, and 3 represent a given level of scientific substantiation or proof. Level 4 or Grade D represents unproven claims. It is the "best evidence" based on the individual ratings of clinical reports that contributes to a final grade recommendation (see the "Rating Scheme for the Strength of the Recommendations" field).

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Current guidelines for clinical practice guidelines (CPG) in clinical medicine emphasize an evidence-based approach rather than simply expert opinion. Even though a purely evidence-based approach lacks applicability to all actual clinical scenarios, its incorporation in these CPG provides objectivity.

Transparency: Levels of Scientific Substantiation and Recommendation Grades

All clinical data that are incorporated in these CPG have been evaluated in terms of levels of scientific substantiation (evidence levels **[EL]**; see the "Rating Scheme

for the Strength of the Evidence" field). This evidence rating system has one minor modification in comparison with the original American Association of Clinical Endocrinologists (AACE) protocol in that level 2 **[EL 2]** prospective studies may be randomized or nonrandomized to allow for well-designed cohort studies. This modification was incorporated because it is difficult to perform well-controlled, randomized clinical trials in surgery, unlike what physicians have been accustomed to in pharmaceutical trials. Another point worth mentioning is that when consensus statements are cited, even if based on a synthesis of evidence as in a published "evidence-based report," then an evidence level 4 **[EL 4]** has been assigned. Every clinical reference was assigned an evidence rating, which has then been inserted in brackets at the end of the citation in both the text and the reference sections. The "best evidence" rating level **[BEL]** corresponds to the best conclusive evidence found. The **BEL** accompanies the recommendation **Grade** in the **Executive Summary** (see "Major Recommendations field) and maps to the text in the **Appendix** section of the original guideline document, where transparency is paramount. In the **Executive Summary**, **BEL 2** ratings have been designated as "randomized," "nonrandomized," or both for additional transparency.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

American Association of Clinical Endocrinologists (AACE), the Obesity Society (TOS), and American Society for Metabolic and Bariatric Surgery (ASMBS) task forces were assembled concurrently to produce these clinical practice guidelines (CPG), as mandated by their respective Board of Directors. Cochairmen and primary writing teams were assigned, and their initial draft was then reviewed by additional AACE, TOS, and ASMBS members before further review by various AACE, TOS, and ASMBS committees.

Final recommendation **Grades** (see the "Rating Scheme for the Strength of the Recommendations" field) incorporate evidence level **(EL)** ratings, and in situations in which there was no clinical evidence, various subjective factors were considered: physician preferences, costs, risks, and regional availability of specific technologies and expertise. Hence, recommendation grades are generally based on strong "best evidence" level **(BEL) (Grade A; BEL 1)**, intermediate **BEL (Grade B; BEL 2)**, weak **BEL (Grade C; BEL 3)**, or subjective factors when there is no clinical evidence, inconclusive clinical evidence, or contradictory clinical evidence **(Grade D; BEL 4)**. All recommendations resulted from a consensus among the AACE, TOS, and ASMBS primary writers and influenced by input from reviewers. If subjective factors take priority over the **BEL** on the basis of the expert opinion of the task force members, then this is described explicitly. Thus, some recommendations may be "upgraded" or "downgraded" according to explicitly stated subjective factors. Furthermore, the correctness of the recommendation **Grades** and **EL** was subject to review at several levels. Also, recommendation **Grades** were assigned only if a specific action is recommended. The action may be ordering a particular diagnostic test, using a particular drug, performing a particular procedure, or adhering to a particular algorithm.

Most of the content is based on literature reviews. In areas of uncertainty, professional judgment was applied.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grade-Recommendation Protocol Adopted by the American Association of Clinical Endocrinologists, The Obesity Society, and American Society for Metabolic & Bariatric Surgery*

Grade	Description	Recommendation
A	≥1 conclusive level 1 publications demonstrating benefit >> risk	Action recommended for indications reflected by the published reports Action based on **strong** evidence Action can be used with other conventional therapy or as **"first-line" therapy**
B	No conclusive level 1 publication ≥1 conclusive level 2 publications demonstrating benefit >> risk	Action recommended for indications reflected by the published reports *If* the patient refuses or fails to respond to conventional therapy; must monitor for adverse effects, if any Action based on **intermediate** evidence Can be recommended as **"second-line" therapy**
C	No conclusive level 1 or 2 publication ≥1 conclusive level 3 publications demonstrating benefit >> risk *or* No risk at all and no benefit at all	Action recommended for indications reflected by the published reports *If* the patient refuses or fails to respond to conventional therapy, provided there are no significant adverse effects; **"no objection" to recommending their use** *or* **"No objection" to continuing their use** Action based on **weak** evidence
D	No conclusive level 1, 2, or 3 publication demonstrating benefit >> risk Conclusive level 1, 2, or 3	**Not recommended** Patient is advised to **discontinue use** Action not based on any evidence

Grade	Description	Recommendation
	publications demonstrating risk >> benefit	

*The final recommendation grades were determined by the primary writers by consensus on the basis of (1) "best evidence" ratings (see "Levels of Scientific Substantiation" table above) and (2) subjective factors.

COST ANALYSIS

Published cost analyses were reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The initial draft was reviewed by members of American Association of Clinical Endocrinologists (AACE), the Obesity Society (TOS), and American Society for Metabolic and Bariatric Surgery (ASMBS) before further review by various AACE, TOS, and ASMBS committees. Finally, the cochairmen performed a review prior to publication.

These clinical practice guidelines (CPG) for perioperative nonsurgical management of the bariatric surgery patient are in strict accordance with the AACE Task Force CPG protocols and have been approved by TOS and ASMBS.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The levels of evidence (1 to 4) and the recommendation grades (A to D) are defined at the end of the "Major Recommendations" field.

Executive Summary of Recommendations

The following recommendations (labeled "**R**") are evidence-based (Grades A, B, and C) or based on expert opinion because of a lack of conclusive clinical evidence (Grade D). The "best evidence" rating level (**BEL**), which corresponds to the best conclusive evidence found, accompanies the recommendation grade in this Executive Summary. Details regarding the mapping of clinical evidence ratings to these recommendation grades are provided in the Appendix (Section 9, "Discussion of the Clinical Evidence") of the original guideline document.

Which Patients Should Be Offered Bariatric Surgery?

The selection criteria and exclusion factors for bariatric surgery are outlined in Table 7 of the original guideline document.

R1. Patients with a body mass index (BMI) ≥40 kg/m^2 for whom bariatric surgery would not be associated with excessive risk should be eligible for one of the procedures **(Grade A; BEL 1)**.

R2. Patients with a BMI ≥35 kg/m^2 and one or more severe comorbidities, including coronary artery disease (CAD), type 2 diabetes mellitus (T2DM), obstructive sleep apnea (OSA), obesity-hypoventilation syndrome (OHS), Pickwickian syndrome (a combination of OSA and OHS), nonalcoholic fatty acid disease (NAFLD) or nonalcoholic steatohepatitis, hypertension, dyslipidemia, pseudotumor cerebri, gastroesophageal reflux disease (GERD), asthma, venous stasis disease, severe urinary incontinence, debilitating arthritis, or considerably impaired quality of life, may also be offered a bariatric procedure if the surgical risks are not excessive **(Grade A; BEL 1)**.

R3. Currently, insufficient data are available to recommend bariatric surgery for patients with a BMI <35 kg/m^2 **(Grade D)**.

R4. There is insufficient evidence for recommending bariatric surgery specifically for glycemic control independent of BMI criteria **(Grade D)**.

Which Bariatric Surgical Procedure Should Be Offered?

R5. The best choice for any bariatric procedure (type of procedure and type of approach) depends on the available local-regional expertise (surgeon and institution), patient preferences, risk stratification, and other idiosyncratic factors, with which the referring physician (or physicians) must become familiar **(Grade D)**. At this time, there is insufficient conclusive evidence to recommend specific bariatric surgical procedures for the general severely obese population **(Grade D)**. Specialists in bariatric medicine, however, must also familiarize themselves with the outcome data among the various bariatric surgical procedures **(Grade D)**. Physicians should exercise caution when recommending biliopancreatic diversion (BPD), BPD with duodenal switch (BPD/DS), or related procedures because of greater associated risks reported in the literature **(Grade C; BEL 3)**.

Table: Types of Bariatric Surgical Procedures

Primary
Vertical banded gastroplasty
Gastric banding
Silastic ring gastroplasty
Laparoscopic adjustable gastric band (LAGB)
Roux-en-Y gastric bypass

Standard

Long-limb

Distal

Biliopancreatic diversion (BPD)

BPD with duodenal switch (BPD/DS)

Staged restrictive and malabsorptive procedure

Secondary

Reversal of gastric restriction

Revision of Roux-en-Y gastric bypass

Revision of BPD

Revision of BPD/DS

Conversion of LAGB to Roux-en-Y gastric bypass

Conversion of LAGB to BPD or BPD/DS

Investigational

Gastric bypass with LAGB

Robotic procedures

Endoscopic (oral)-assisted techniques

Gastric balloon

Gastric pacer

Vagus nerve pacing

Vagus nerve block

Sleeve gastrectomy

R6. Although risks and benefits are associated with both approaches, laparoscopic bariatric procedures are preferred over open bariatric procedures if sufficient surgical expertise is available **(Grade B; BEL 2 [randomized and nonrandomized])**.

R7. A first-stage sleeve gastrectomy may be performed in high-risk patients to induce an initial weight loss (25 to 45 kg), with the possibility of then performing a second-stage Roux-en-Y gastric bypass (RYGB) or BPD/DS after the patient's operative risk has improved. This is currently an investigational procedure **(Grade C; BEL 3)**.

How Should Potential Candidates for Bariatric Surgery Be Managed Preoperatively?

R8. All patients should undergo evaluation for causes and complications of obesity, with special attention directed to those factors that could affect a recommendation for bariatric surgery (see Table 8 in the original guideline document) **(Grade A; BEL 1)**.

R9. The preoperative evaluation must include a comprehensive medical history, physical examination, and appropriate laboratory testing **(Grade A; BEL 1)**.

R10. The medical necessity for bariatric surgery should be documented **(Grade D)**.

R11. There should be a thorough discussion with the patient regarding the risks and benefits, procedural options, and choices of surgeon and medical institution **(Grade D)**.

R12. Patients should be provided with educational materials and access to preoperative educational sessions at prospective bariatric surgery centers **(Grade D)**.

R13. Financial counseling should be provided, and the physician should be able to provide all necessary clinical material for documentation so that third-party payer criteria for reimbursement are met **(Grade D)**.

R14. Preoperative weight loss should be considered in patients in whom reduction of liver volume can improve the technical aspects of surgery **(Grade B; BEL 2 [nonrandomized])**.

System-Oriented Approach to Medical Clearance for Bariatric Surgery

Endocrine

Diabetes

R15. Preoperative glycemic control should be optimized with use of medical nutrition therapy and physical activity; orally administered agents and insulin should be introduced as needed **(Grade D)**.

R16. Reasonable targets for preoperative glycemic control should be a hemoglobin A1c value of 7.0% or less, a fasting blood glucose level of 110 mg/dL or less, and a 2-hour postprandial blood glucose concentration of 140 mg/dL or less (see http://www.aace.com/pub/pdf/guidelines/DMGuidelines2007.pdf), but

these variables are based on evidence related to long-term outcome and may not be applicable in this setting **(Grade D)**.

R17. A protocol for perioperative glycemic control should be reviewed *before* the patient undergoes bariatric surgery **(Grade D)**.

Thyroid

R18. Routine screening recommendations for hypothyroidism are conflicting. When thyroid disease is suspected, a sensitive serum thyroid-stimulating hormone level should be ordered **(Grade D)**.

R19. In patients found to have thyroid dysfunction, treatment should be initiated before bariatric surgery **(Grade D)**.

Lipids

R20. A fasting lipid panel should be obtained in all patients with obesity **(Grade A; BEL 1)**.

R21. Treatment should be initiated according to the National Cholesterol Education Program Adult Treatment Panel III guidelines (see http://www.nhlbi.nih.gov/guidelines/cholesterol/) **(Grade D)**.

Polycystic Ovary Syndrome (PCOS) and Fertility

R22. Candidates for bariatric surgery should minimize the risk of pregnancy for at least 12 months perioperatively **(Grade C; BEL 3)**.

R23. All women of reproductive age should be counseled on contraceptive choices **(Grade D)**.

R24. Women with a laparoscopic adjustable gastric band (LAGB) should be closely monitored during pregnancy because band adjustment may be necessary **(Grade B; BEL 2 [nonrandomized])**.

R25. Estrogen therapy should be discontinued before bariatric surgery (1 cycle of oral contraceptives in premenopausal women; 3 weeks of hormone replacement therapy in postmenopausal women) to reduce the risks for postoperative thromboembolic phenomena **(Grade D)**.

R26. Women with PCOS should be advised that their fertility status may be improved postoperatively **(Grade D)**.

Exclusion of Endocrine Causes of Obesity

R27. Routine laboratory testing to screen for rare causes of obesity (for example, Cushing syndrome, hypothalamic obesity syndromes, melanocortin-4 mutations, and leptin deficiency obesity) is not cost-effective and not recommended **(Grade D)**.

R28. Case-by-case decisions to screen for rare causes of obesity should be based on specific historical and physical findings **(Grade D)**.

Cardiology and Hypertension

R29. Noninvasive testing beyond an electrocardiogram is determined on the basis of the individual risk factors and findings on history and physical examination **(Grade D)**.

R30. Patients with known cardiac disease should have a formal cardiology consultation before bariatric surgery **(Grade D)**.

R31. Patients at risk for heart disease should undergo evaluation for perioperative beta-adrenergic blockade **(Grade A; BEL 1)**.

Pulmonary and Sleep Apnea

R32. All patients considered for bariatric surgery should have a chest radiograph preoperatively **(Grade D)**.

R33. Patients with intrinsic lung disease or disordered sleep patterns should have a formal pulmonary evaluation, including arterial blood gas measurement and polysomnography, when knowledge of the results would alter patient care **(Grade D)**.

R34. Patients should stop smoking at least 8 weeks before bariatric surgery and should plan to quit smoking or to participate in a smoking cessation program postoperatively **(Grade C; BEL 3)**.

Venous Disease

R35. Patients at risk for, or with a history of, deep venous thrombosis (DVT) or cor pulmonale should undergo an appropriate diagnostic evaluation for DVT **(Grade D)**.

R36. A prophylactic vena caval filter should be considered for patients with a history of prior pulmonary embolus (PE), prior iliofemoral DVT, evidence of venostasis, known hypercoagulable state, or increased right-sided heart pressures **(Grade C; BEL 3)**.

Gastrointestinal

R37. All gastrointestinal symptoms should be evaluated and treated before bariatric surgery **(Grade D)**.

R38. All patients considered for bariatric surgery who have increased liver function test results (2 to 3 times the upper limit of normal) should undergo abdominal ultrasonography and a viral hepatitis screen **(Grade D)**.

R39. There is inconsistent evidence to recommend routine screening for the presence of *Helicobacter pylori* before bariatric surgery **(Grade D)**.

Rheumatologic and Metabolic Bone Disease

R40. There are no evidence-based, routine preoperative tests required for evaluation of rheumatologic problems **(Grade D)**.

R41. There are insufficient data to warrant routine preoperative assessment of bone mineral density with dual-energy x-ray absorptiometry **(Grade D)**.

Psychiatric

R42. A psychosocial-behavioral evaluation, which assesses environmental, familial, and behavioral factors, should be considered for all patients before bariatric surgery **(Grade D)**.

R43. Any patient considered for bariatric surgery with a known or suspected psychiatric illness should undergo a formal mental health evaluation before performance of the surgical procedure **(Grade C; BEL 3)**.

R44. All patients should undergo evaluation of their ability to incorporate nutritional and behavioral changes before and after bariatric surgery **(Grade D)**.

Nutritional

R45. All patients should undergo an appropriate nutritional evaluation, including selective micronutrient measurements (see Tables 13 and 17 in the original guideline document), before any bariatric surgical procedure **(Grade C; BEL 3)**. In comparison with purely restrictive procedures, more extensive perioperative nutritional evaluations are required for malabsorptive procedures.

Early Postoperative Care (<5 Days)

Nutrition

R46. A clear liquid meal program can usually be initiated within 24 hours after any of the bariatric procedures, but this schedule should be discussed with the surgeon **(Grade C; BEL 3)**.

R47. A consultation should be arranged with a registered dietitian who is a member of the bariatric surgery team **(Grade D)**.

R48. A protocol-derived staged meal progression, based on the type of surgical procedure, should be provided to the patient. Sample protocols are shown in Tables 9, 10, and 11 of the original guideline document **(Grade D)**.

R49. Nutrition and meal planning guidance should be provided to the patient and family before bariatric surgery and during the postoperative hospital course and reinforced during future outpatient visits **(Grade D)**.

R50. Patients should adhere to a plan of multiple small meals each day, chewing their food thoroughly without drinking beverages at the same time (more than 30 minutes apart) **(Grade D)**.

R51. Patients should be advised to adhere to a balanced meal plan that consists of more than 5 servings of fruits and vegetables daily for optimal fiber consumption, colonic function, and phytochemical consumption **(Grade D)**.

R52. Protein intake should average 60 to 120 g daily **(Grade D)**.

R53. Concentrated sweets should be avoided after RYGB to minimize symptoms of the dumping syndrome or after any bariatric procedure to reduce caloric intake **(Grade D)**.

R54. Minimal nutritional supplementation includes 1 to 2 adult multivitamin-mineral supplements containing iron, 1,200 to 1,500 mg/day (d) of calcium, and a vitamin B-complex preparation **(Grade B; BEL 2 [nonrandomized])**.

R55. Fluids should be consumed slowly and in sufficient amounts to maintain adequate hydration (more than 1.5 L daily) **(Grade D)**.

R56. Parenteral nutrition (PN) should be considered in high-risk patients, such as critically ill patients unable to tolerate sufficient enteral nutrition for more than 5 to 7 days or noncritically ill patients unable to tolerate sufficient enteral nutrition for more than 7 to 10 days **(Grade D)**.

Diabetes

R57. In patients with T2DM, periodic fasting blood glucose concentrations should be determined. Preprandial and bedtime reflectance meter glucose ("finger-stick") determinations in the home setting should be encouraged, depending on the patient's ability to test and the level of glycemic control. Finger-stick glucose determinations should also be performed if symptoms of hypoglycemia occur **(Grade A; BEL 1)**.

R58. Use of all insulin secretagogue drugs (sulfonylureas and meglitinides) should be discontinued **(Grade D)**.

R59. In non-intensive care unit (ICU) hospitalized patients, a rapid-acting insulin analogue should be administered before meals and at bedtime to maintain maximal postprandial values below 180 mg/dL **(Grade D)**.

R60. In non-ICU hospitalized patients, fasting blood glucose levels should be maintained between 80 and 110 mg/dL with the use of a long-acting insulin analogue, such as insulin glargine (Lantus) or detemir (Levemir) **(Grade D)**.

R61. In the ICU, all blood glucose levels should be maintained ideally within the range of 80 to 110 mg/dL by using an intravenous insulin infusion **(Grade A; BEL 1)**.

Cardiology

R62. Patients with known or presumed CAD and high perioperative risk should be managed in an ICU setting for the first 24 to 48 hours postoperatively **(Grade D)**.

R63. Therapy with beta-adrenergic blocking agents should be considered perioperatively for cardioprotection **(Grade D)**.

Pulmonary

R64. Appropriate pulmonary management includes aggressive pulmonary toilet and incentive spirometry, oxygen supplementation to avoid hypoxemia, and early institution of continuous positive airway pressure (CPAP) when clinically indicated **(Grade D)**.

R65. Prophylaxis against DVT is recommended for all patients **(Grade B; BEL 2 [randomized])** and may be continued until patients are ambulatory **(Grade D)**. Early ambulation is encouraged **(Grade C; BEL 3)**.

R66. Currently recommended prophylactic regimens include sequential compression devices **(Grade C; BEL 3)**, as well as subcutaneously administered unfractionated heparin or low-molecular-weight heparin for 3 days before and after bariatric surgery **(Grade B; BEL 2 [randomized])**, and inferior vena cava filter placement in patients at high risk for mortality after PE or DVT **(Grade C; BEL 3)**, with known pulmonary artery pressure exceeding 40 mm Hg **(Grade D)**, or with known hypercoagulable states **(Grade C; BEL 3)**.

R67. Respiratory distress or failure to wean from ventilatory support should raise suspicion and prompt an evaluation for an acute postoperative complication, such as PE or anastomotic leak **(Grade D)**.

Monitoring for Surgical Complications

R68. In the clinically stable patient, meglumine diatrizoate (Gastrografin) upper gastrointestinal (UGI) studies or computed tomography (CT) may identify anastomotic leaks **(Grade C; BEL 3)**.

R69. Exploratory laparotomy is recommended in the setting of high clinical suspicion for anastomotic leaks despite a negative study **(Grade C; BEL 3)**.

R70. The presence of a new sustained pulse rate of more than 120 beats/min for longer than 4 hours should raise suspicion for an anastomotic leak **(Grade D)**.

R71. A routine gastrografin UGI study may be considered to identify any subclinical leaks before discharge of the patient from the hospital **(Grade C; BEL 3)**.

Fluid Management

R72. The goals of fluid management during the early postoperative period after bariatric surgery are maintaining a urine output of more than 40 mL/hour (h), avoiding volume overload, maintaining normal serum electrolyte levels, and limiting dextrose-containing solutions to avoid hyperglycemia **(Grade D)**.

R73. Postoperative urine output must be monitored, with a target of more than 30 mL/h or 240 mL per 8- hour shift **(Grade D)**.

Preventing Rhabdomyolysis

R74. Patients should have adequate padding at all pressure points during bariatric surgery **(Grade D)**.

R75. When rhabdomyolysis is suspected, creatine kinase (CK) levels should be determined **(Grade C; BEL 3)**.

Anemia

R76. The indications for transfusions of blood products after bariatric surgery are the same as for other surgical procedures **(Grade D)**.

R77. Persistence of anemia without evidence of blood loss should be evaluated in terms of nutritional deficiencies during the late postoperative period **(Grade D)**.

Late Postoperative Management (≥5 Days)

Follow-up

R78. The frequency of follow-up depends on the bariatric procedure performed and the severity of comorbidities **(Grade D)** (see Table 12 of the original guideline document).

Weight Loss

R79. Inadequate weight loss should prompt evaluation for (*1*) surgical failure with loss of integrity of the gastric pouch in gastroplasty or RYGB procedures, (*2*) a poorly adjusted gastric band, and (*3*) development of maladaptive eating behaviors or psychologic complications **(Grade B; BEL 2 [randomized])**.

R80. The assessment of inadequate weight loss after bariatric surgery should include imaging studies to determine the integrity of the gastric pouch, ascertainment of the patient's understanding of the meal plan and compliance, and psychologic evaluation **(Grade D)**.

R81. Inadequate weight loss after a bariatric procedure without resolution or a recurrence of a major comorbidity may necessitate a surgical revision, such as conversion of a LAGB to either a RYGB or a BPD/DS **(Grade D)**.

Metabolic and Nutritional Management

R82. In those patients without complete resolution of their T2DM, hyperlipidemia, or hypertension, continued surveillance and management should be guided by currently accepted practice guidelines for those conditions **(Grade D)**.

R83. In those patients in whom T2DM, hyperlipidemia, and hypertension have resolved, continued surveillance should be guided by recommended screening guidelines for the specific age-group **(Grade D)**.

R84. Patients who have undergone RYGB, BPD, or BPD/DS and who present with postprandial hypoglycemic symptoms that have not responded to nutritional manipulation should undergo evaluation for the possibility of endogenous hyperinsulinemic hypoglycemia **(Grade C; BEL 3)**.

R85. Routine metabolic and nutritional monitoring is recommended after all bariatric surgical procedures **(Grade A; BEL 1)**.

R86. Patients should be advised to increase their physical activity (aerobic and strength training) to a minimum of 30 minutes per day as well as increase physical activity throughout the day as tolerated **(Grade D)**.

R87. All patients should be encouraged to participate in ongoing support groups after discharge from the hospital **(Grade D)**.

Association of Malabsorptive Surgical Procedures with Nutritional Deficiencies

R88. The frequency and recommended nutritional surveillance in patients who have had a malabsorptive bariatric procedure are outlined in Table 13 of the original guideline document **(Grade C; BEL 3)**.

R89. The recommended empiric vitamin and mineral supplementation after malabsorptive bariatric surgery is outlined in Table 14 of the original guideline **(Grade B; BEL 2 [randomized and nonrandomized])**.

Protein Depletion and Supplementation

R90. Protein intake should be quantified periodically **(Grade D)**.

R91. Ideally, protein intake with meals, including protein supplementation, should be in the range of 80 to 120 g/d for patients with a BPD or BPD/DS and 60 g/d or more for those with RYGB **(Grade D)**.

R92. In patients with severe protein malnutrition not responsive to oral protein supplementation, PN should be considered **(Grade D)**.

Skeletal and Mineral Homeostasis, Including Nephrolithiasis

R93. Recommended laboratory tests for the evaluation of calcium and vitamin D metabolism and metabolic bone disease in patients who have undergone RYGB, BPD, or BPD/DS are outlined in Table 15 of the original guideline document **(Grade D)**.

R94. In patients who have undergone RYGB, BPD, or BPD/DS, treatment with orally administered calcium, ergocalciferol (vitamin D_2), or cholecalciferol (vitamin D_3) is indicated to prevent or minimize secondary hyperparathyroidism without inducing frank hypercalciuria **(Grade C; BEL 3)**.

R95. In cases of severe vitamin D malabsorption, oral doses of vitamin D_2 or D_3 may need to be as high as 50,000 to 150,000 units (U) daily, and more

recalcitrant cases may require concurrent oral administration of calcitriol (1,25-dihydroxyvitamin D) **(Grade D)**.

R96. In patients with RYGB, BPD, or BPD/DS, bone density measurements with use of dual-energy x-ray absorptiometry may be indicated to monitor for the development or presence of osteoporosis at baseline, in addition to a follow-up study at about 2 years, in accordance with the recommendations from the International Society for Clinical Densitometry (http://www.iscd.org/Visitors/positions/OfficialPositionsText.cfm?from_home=1) and the National Osteoporosis Foundation (http://www.nof.org/osteoporosis/bonemass.htm) **(Grade D)**.

R97. Bisphosphonates approved by the US Food and Drug Administration may be a consideration in bariatric surgery patients with osteoporosis (*T* score -2.5 or below for the hip or spine) only after adequate and appropriate evaluation and therapy for calcium and vitamin D insufficiency. This evaluation should include and confirm a normal parathyroid hormone (PTH) level, 25-hydroxyvitamin D level of 30 to 60 ng/mL, normal serum calcium level, normal phosphorus level, and 24-hour urine calcium excretion between about 70 and 250 mg/24 hours. Therapy considerations should be based on the National Osteoporosis Foundation-World Health Organization 2008 Guidelines (http://www.nof.org/professionals/Clinicians_Guide.htm). If therapy is indicated, then intravenously administered bisphosphonates should be used if concerns exist about adequate oral absorption and potential anastomotic ulceration with use of orally administered bisphosphonates **(Grade C; BEL 3)**.

R98. Recommended dosages of orally administered bisphosphonates in bariatric surgery patients with osteoporosis include the following: alendronate, 70 mg/week; risedronate, 35 mg/week or two 75-mg tablets/month; or ibandronate, 150 mg/month. Recommended intravenous dosages of bisphosphonates are as follows: zoledronic acid, 5 mg once a year, or ibandronate, 3 mg every 3 months **(Grade D)**.

R99. There are insufficient data to recommend empiric supplementation of magnesium after bariatric surgery beyond what is included in a mineral-containing multivitamin that provides the daily recommended intake of magnesium (>300 mg in women; >400 mg in men) **(Grade D)**.

R100. Oral phosphate supplementation may be provided for mild to moderate hypophosphatemia (1.5 to 2.5 mg/dL), which is usually due to vitamin D deficiency **(Grade D)**.

R101. Management of oxalosis and calcium oxalate stones includes avoidance of dehydration, a low oxalate meal plan, and oral calcium and potassium citrate therapy **(Grade D)**.

R102. Probiotics containing *Oxalobacter formigenes* have been shown to improve renal oxalate excretion and improve supersaturation levels and may therefore be used as well **(Grade C; BEL 3)**.

Fat and Fat-Soluble Vitamin Malabsorption

R103. The routine use of serum fatty acid chromatography to detect essential fatty acid deficiency is not cost-effective and should not be performed because this deficiency has not been reported **(Grade D)**.

R104. Routine supplementation of vitamin A is usually not necessary after RYGB or purely restrictive procedures **(Grade C; BEL 3)**.

R105. In contrast, routine screening for vitamin A deficiency is recommended, and supplementation is often needed after malabsorptive bariatric procedures, such as BPD or BPD/DS **(Grade C; BEL 3)**.

R106. Supplementation may be provided with use of vitamin A alone or in combination with the other fat-soluble vitamins (D, E, and K) **(Grade C; BEL 3)**.

R107. The value of routine screening for vitamin E or K deficiencies has not been documented for any bariatric procedure, including BPD and BPD/DS **(Grade C; BEL 3)**.

R108. In the presence of an established fat-soluble vitamin deficiency with hepatopathy, coagulopathy, or osteoporosis, assessment of a vitamin K_1 level should be considered in an effort to detect a deficiency state **(Grade D)**.

Iron, Vitamin B_{12}, Folic Acid, and Selenium Deficiencies; the Nutritional Anemias

R109. Iron status should be monitored in all bariatric surgery patients and then appropriately treated as in any medical or surgical patient **(Grade D)**.

R110. Orally administered ferrous sulfate, fumarate, or gluconate (320 mg twice a day) may be needed to prevent iron deficiency in patients who have undergone a malabsorptive bariatric surgical procedure, especially in menstruating women **(Grade A; BEL 1)**.

R111. Vitamin C supplementation should be considered in patients with recalcitrant iron deficiency because vitamin C can increase iron absorption and ferritin levels **(Grade C; BEL 3)**.

R112. Intravenous iron infusion with iron dextran, ferric gluconate, or ferric sucrose may be needed if oral iron supplementation is ineffective at correcting the iron deficiency **(Grade D)**.

R113. Evaluation for vitamin B_{12} deficiency is recommended in all bariatric surgery patients **(Grade B; BEL 2 [nonrandomized])**.

R114. Oral supplementation with crystalline vitamin B_{12} at a dosage of 350 micrograms daily or more or intranasally administered vitamin B_{12}, 500 micrograms weekly, may be used to maintain vitamin B12 levels **(Grade B; BEL 2 [nonrandomized])**.

R115. Parenteral supplementation with either 1,000 micrograms of vitamin B_{12} monthly or 1,000 to 3,000 micrograms every 6 to 12 months is necessary if

vitamin B_{12} sufficiency cannot be maintained by means of oral supplementation **(Grade C; BEL 3)**.

R116. Assessment of vitamin B_{12} status should be done annually in patients who have undergone RYGB or BPD/DS **(Grade D)**.

R117. Folic acid supplementation (400 micrograms/d) is provided as part of a routine multivitamin preparation **(Grade B; BEL 2 [randomized and nonrandomized])**.

R118. Folic acid supplementation should be provided in all women of childbearing age because of the risk of fetal neural tube defects with folic acid deficiency **(Grade A; BEL 1)**.

R119. Nutritional anemias resulting from malabsorptive bariatric surgical procedures might also involve deficiencies in protein, copper, and selenium, necessitating evaluation of these nutrients when routine screening for iron, vitamin B_{12}, and folic acid deficiencies is negative **(Grade C; BEL 3)**.

R120. There are insufficient data to support routine screening for selenium deficiency or empiric selenium supplementation in patients after a bariatric surgical procedure **(Grade D)**.

R121. In patients treated with BPD or BPD/DS who have unexplained anemia or fatigue, persistent diarrhea, cardiomyopathy, or metabolic bone disease, selenium levels should be checked **(Grade C; BEL 3)**.

<u>Zinc and Thiamine</u>

R122. Because zinc deficiency has been described, physicians should routinely screen for it after BPD or BPD/DS, while bearing in mind that plasma zinc levels are unreliable in the presence of systemic inflammation **(Grade C; BEL 3)**.

R123. There is inadequate clinical evidence to recommend empiric zinc supplementation after bariatric surgery **(Grade D)**.

R124. All bariatric surgery patients should be provided with an oral multivitamin supplement that contains thiamine **(Grade D)**.

R125. Routine screening for thiamine deficiency or additional empiric thiamine treatment (or both) is not recommended in bariatric surgery patients who are already routinely receiving a multivitamin supplement that contains thiamine **(Grade C; BEL 3)**.

R126. Patients with protracted vomiting should be screened for thiamine deficiency **(Grade C; BEL 3)**.

R127. In patients with persistent vomiting after *any* bariatric procedure, aggressive supplementation with thiamine is imperative; intravenously administered glucose should be provided judiciously in this situation because it can aggravate thiamine deficiency **(Grade C; BEL 3)**.

R128. In patients presenting with neurologic symptoms suggestive of thiamine deficiency (that is, Wernicke encephalopathy and peripheral neuropathy), aggressive parenteral supplementation with thiamine (100 mg/d) should be administered for 7 to 14 days **(Grade C; BEL 3)**.

R129. Subsequent oral thiamine supplementation (100 mg/d) should be continued until neurologic symptoms resolve **(Grade C; BEL 3)**.

Cardiology and Hypertension

R130. Lipid levels and need for lipid-lowering medications should be periodically monitored and evaluated **(Grade D)**.

R131. Use of antihypertensive medications should be evaluated repeatedly and reduced or discontinued as indicated with the resolution of hypertension **(Grade D)**.

Gastrointestinal Complications

Diarrhea

R132. If diarrhea persists, an evaluation should be initiated **(Grade C; BEL 3)**.

R133. Upper endoscopy with small bowel biopsies and aspirates remains the "gold standard" in the evaluation of celiac sprue **(Grade C; BEL 3)** and bacterial overgrowth **(Grade C; BEL 3)**.

R134. Colonoscopy should be performed and a stool specimen should be obtained if the presence of *Clostridium difficile* colitis is suspected **(Grade C; BEL 3)**.

R135. Persistent steatorrhea after BPD or BPD/DS should prompt an evaluation for nutrient deficiencies **(Grade C; BEL 3)**.

Stomal Stenosis or Ulceration after Bariatric Surgery

R136. Nonsteroidal anti-inflammatory drugs should be avoided after bariatric surgery because they have been implicated in the development of anastomotic ulcerations **(Grade C; BEL 3)**.

R137. Alternative pain medication should be identified before bariatric surgery **(Grade D)**.

R138. Persistent and severe gastrointestinal symptoms (such as nausea, vomiting, and abdominal pain) warrant additional evaluation **(Grade C; BEL 3)**.

R139. Upper intestinal endoscopy is the preferred diagnostic procedure because, in many circumstances, upper endoscopy can also incorporate a therapeutic intervention with transendoscopic dilation of a recognized stricture **(Grade C; BEL 3)**.

R140. Evaluation should include *Helicobacter pylori* testing as a possible contributor to persistent gastrointestinal symptoms after bariatric surgery **(Grade C; BEL 3)**.

R141. Anastomotic ulcers should be treated with H_2 receptor blockers, proton pump inhibitors, sucralfate, antibiotics, and, if *H pylori* is identified, multiple antibiotics and bismuth **(Grade C; BEL 3)**.

R142. Patients who previously underwent a RYGB with a nonpartitioned stomach and develop a gastro-gastric fistula should undergo revisional RYGB to separate the upper and lower gastric pouches **(Grade D)**.

R143. Persistent vomiting, regurgitation, and UGI obstruction after LAGB should be treated with immediate removal of all fluid from the adjustable band **(Grade D)**.

R144. Persistent symptoms of gastroesophageal reflux, regurgitation, chronic cough, or recurrent aspiration pneumonia after LAGB are all problems suggestive of the band being too tight or the development of an abnormally large gastric pouch above the band. These symptoms should prompt immediate referral back to the surgeon **(Grade D)**.

Gallbladder Disease

R145. Oral administration of ursodiol (300 mg twice a day) for 6 months postoperatively may be considered in patients not undergoing a prophylactic cholecystectomy **(Grade A; BEL 1)**.

R146. There is a debate regarding performance of cholecystectomy for known gallstones at the time of RYGB, BPD, or BPD/DS procedures. There is no consensus regarding the need to perform cholecystectomy at the time of bariatric operations **(Grade C; BEL 3)**.

Bacterial Overgrowth

R147. Although uncommon, suspected bacterial overgrowth in the biliopancreatic limb after BPD or BPD/DS should be treated empirically with metronidazole **(Grade C; BEL 3)**.

R148. For antibiotic-resistant cases of bacterial overgrowth, probiotic therapy with *Lactobacillus plantarum* 299v and *Lactobacillus* GG may be considered **(Grade D)**.

Incisional Hernias

R149. Repair of asymptomatic hernias should be deferred until weight loss has stabilized and nutritional status has improved, to allow for adequate healing (12 to 18 months after bariatric surgery) **(Grade D)**.

R150. Incarcerated incisional or umbilical hernias in conjunction with abdominal pain necessitates aggressive surgical correction because of the risk of bowel infarction **(Grade C; BEL 3)**.

Bowel Obstruction from Adhesions or Internal Hernias

R151. Patients with cramping periumbilical pain at any time after RYGB, BPD, or BPD/DS should be emergently evaluated with an abdominal and pelvic CT scan to exclude the potentially life-threatening complication of closed-loop bowel obstruction **(Grade D)**.

R152. Exploratory laparotomy or laparoscopy is indicated in patients who are suspected of having an internal hernia because this complication can be missed with UGI studies and CT scans **(Grade C; BEL 3)**.

Body-Contouring Surgery

R153. Body-contouring surgery may be performed after bariatric surgery to manage excess tissue that impairs hygiene, causes discomfort, and is disfiguring **(Grade C; BEL 3)**.

R154. Circumferential torsoplasty or abdominoplasty may be used to remove excess abdominal skin **(Grade D)**.

R155. Breast reduction or lift, arm lift, resection of redundant gluteal skin, and thigh lift can also be pursued **(Grade D)**.

R156. Such procedures are best pursued after weight loss has stabilized (12 to 18 months after bariatric surgery) **(Grade D)**.

R157. Tobacco use must be avoided and nutritional status maintained in bariatric surgery patients undergoing postoperative body-contouring procedures **(Grade A; BEL 1)**.

Criteria for Hospital Admission after Bariatric Surgery

R158. Severe malnutrition should prompt hospital admission for initiation of nutritional support **(Grade D)**.

R159. The initiation of enteral or parenteral nutrition should be guided by established published criteria **(Grade D)**.

R160. Hospital admission is required for the management of gastrointestinal complications after bariatric surgery in clinically unstable patients **(Grade D)**.

R161. Surgical management should be pursued for gastrointestinal complications not amenable or responsive to medical therapy **(Grade D)**.

R162. If not dehydrated, most patients can undergo endoscopic stomal dilation for stricture as an outpatient procedure **(Grade D)**.

R163. Revision of a bariatric surgical procedure is recommended in the following circumstances: (1) presence of medical complications clearly resulting from the surgical procedure and not amenable or responsive to medical therapy (for example, malnutrition) and (2) inadequate weight loss or weight regain in patients with persistent weight-related comorbidities who previously underwent a restrictive procedure (for example, VBG) **(Grade C; BEL 3)**.

R164. Reversal of a bariatric surgical procedure is recommended when serious complications related to previous bariatric surgery cannot be managed medically and are not amenable to surgical revision **(Grade D)**.

Definitions:

Levels of Scientific Substantiation in Evidence-Based Medicine*

Level	Description	Comments
1	Prospective, randomized, controlled trials—large	Data are derived from a substantial number of trials, with adequate statistical power involving a substantial number of outcome data subjects Large meta-analyses using raw or pooled data or incorporating quality ratings Well-controlled trial at one or more centers Consistent pattern of findings in the population for which the recommendation is made (generalizable data) Compelling nonexperimental, clinically obvious, evidence (for example, use of insulin in diabetic ketoacidosis); "all-or-none" indication
2	Prospective controlled trials with or without randomization—limited body of outcome data	Limited number of trials, small population sites in trials Well-conducted single-arm prospective cohort study Limited but well-conducted meta-analyses Inconsistent findings or results not representative for the target population Well-conducted case-controlled study
3	Other experimental outcome data and nonexperimental data	Nonrandomized, controlled trials Uncontrolled or poorly controlled trials

Level	Description	Comments
		Any randomized clinical trial with 1 or more major or 3 or more minor methodologic flaws Retrospective or observational data Case reports or case series Conflicting data with weight of evidence unable to support a final recommendation
4	Expert opinion	Inadequate data for inclusion in level 1, 2, or 3; necessitates an expert panel's synthesis of the literature and a consensus Experience-based Theory-driven

* Levels 1, 2, and 3 represent a given level of scientific substantiation or proof. Level 4 or Grade D represents unproven claims. It is the "best evidence" based on the individual ratings of clinical reports that contributes to a final grade recommendation (see the "Rating Scheme for the Strength of the Recommendations" field).

Grades of Recommendations*

Grade	Description	Recommendation
A	≥1 conclusive level 1 publications demonstrating benefit >> risk	Action recommended for indications reflected by the published reports Action based on **strong** evidence Action can be used with other conventional therapy or as **"first-line" therapy**
B	No conclusive level 1 publication ≥1 conclusive level 2 publications demonstrating benefit >> risk	Action recommended for indications reflected by the published reports *If* the patient refuses or fails to respond to conventional therapy; must monitor for adverse effects, if any Action based on **intermediate** evidence Can be recommended as **"second-line" therapy**
C	No conclusive level 1 or 2 publication	Action recommended for indications reflected by the published reports

Grade	Description	Recommendation
	≥1 conclusive level 3 publications demonstrating benefit >> risk *or* No risk at all and no benefit at all	*If* the patient refuses or fails to respond to conventional therapy, provided there are no significant adverse effects; **"no objection" to recommending their use** *or* **"No objection" to continuing their use** Action based on **weak** evidence
D	No conclusive level 1, 2, or 3 publication demonstrating benefit >> risk Conclusive level 1, 2, or 3 publications demonstrating risk >> benefit	**Not recommended** Patient is advised to **discontinue use** Action not based on any evidence

*The final recommendation grades were determined by the primary writers by consensus on the basis of (1) "best evidence" ratings (see "Levels of Scientific Substantiation" table above) and (2) subjective factors.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Improved perioperative nutritional, metabolic, and nonsurgical support of bariatric surgery patients

POTENTIAL HARMS

Surgical and nutritional complications (including mortality) of bariatric surgery

CONTRAINDICATIONS

CONTRAINDICATIONS

- Currently, a consensus does not exist on the possible contraindications to bariatric surgery. Suggested contraindications would include an extremely high operative risk (such as severe congestive heart failure or unstable angina), active substance abuse, or a major psychopathologic condition. Patients who cannot comprehend the nature of the surgical intervention and the lifelong measures required to maintain an acceptable level of health should not be offered these procedures.
- Persistent alcohol and drug dependence, uncontrolled severe psychiatric illness such as depression or schizophrenia, or cardiopulmonary disease are contraindications to bariatric surgery. Although these patients have a significantly increased risk of mortality, they should expect profound improvements in their weight-related pathologic condition if they can survive the bariatric procedure. Better risk-to-benefit stratification is needed for this group of patients.

QUALIFYING STATEMENTS

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- These guidelines are a working document that reflects the state of the field at the time of publication. Because rapid changes in this area are expected, periodic revisions are inevitable. The guideline developers encourage medical professionals to use this information in conjunction with their best clinical judgment. The presented recommendations may not be appropriate in all situations. Any decision by practitioners to apply these guidelines must be made in light of local resources and individual patient circumstances.
- Shortcomings of the evidence-based methodology in these clinical practice guidelines (CPG) are (1) relative paucity of strong (level 1 and 2) scientific data, leaving the majority of recommendations based on weaker, extant evidence level **(EL) 3** data and **EL 4** consensus opinion; (2) subjectivity on the part of the primary writers when weighing positive and negative, or epidemiologic versus experimental, data to arrive at an evidence-based recommendation grade or consensus opinion; (3) subjectivity on the part of the primary writers when weighing subjective attributes, such as cost-effectiveness and risk-to-benefit ratios, to arrive at an evidence-based recommendation **Grade** or consensus opinion; (4) potentially incomplete review of the literature by the primary writers despite extensive diligence; and (5) bias in the available publications which originate predominantly from experienced bariatric surgeons and surgery centers and may therefore not reflect the experience at large. These shortcomings have been addressed by the primary writers through an a priori methodology and multiple levels of review by a large number of experts from the 3 participating societies.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Mechanick JI, Kushner RF, Sugerman HJ, Gonzalez-Campoy JM, Collazo-Clavell ML, Guven S, Spitz AF, Apovian CM, Livingston EH, Brolin R, Sarwer DB, Anderson WA, Dixon J. American Association of Clinical Endocrinologists, The Obesity Society, and American Society for Metabolic & Bariatric Surgery Medical guidelines for clinical practice for the perioperative nutritional, metabolic, and nonsurgical support [trunc]. Endocr Pract 2008 Jul-Aug;14 Suppl 1:1-83. [777 references] PubMed

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Not applicable: The guideline was not adapted from another source.

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The Obesity Society - Disease Specific Society

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Cochairmen

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Dr. Harvey J. Sugerman reports that he has received speaker honoraria from Ethicon Endo-Surgery, Inc., consultant fees from EnteroMedics, salary for his role as Editor from Surgery for Obesity and Related Diseases (official journal of the American Society for Metabolic & Bariatric Surgery), and salary for his role as Review Committee Chair from Surgical Review Corporation.

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Refer to the original guideline document for disclosure information relevant to guideline reviewers.

GUIDELINE STATUS

This is the current release of the guideline.

These clinical practice guidelines (CPG) will expire in 2011 and will be updated by American Association of Clinical Endocrinologists (AACE), the Obesity Society (TOS), and American Society for Metabolic and Bariatric Surgery (ASMBS) at a time determined by the societies.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American Association of Clinical Endocrinologists (AACE) Web site.

Print copies: Available from the American Association of Clinical Endocrinologists (AACE), 245 Riverside Ave, Suite 200, Jacksonville, FL 32202.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- American Association of Clinical Endocrinologists protocol for standardized production of clinical practice guidelines. Endocrine Pract 2004 Jul/Aug; 10(4):353-61.

Electronic copies: Available in Portable Document Format (PDF) from the American Association of Clinical Endocrinologists (AACE) Web site.

Print copies: Available from the American Association of Clinical Endocrinologists (AACE), 245 Riverside Ave, Suite 200, Jacksonville, FL 32202.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on January 6, 2009. The information was verified by the guideline developer on January 16, 2009.

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